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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,335	05/20/2008	Philippe Perovitch	0603-1002	2717

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
05/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,335	PEROVITCH ET AL.	
	Examiner	Art Unit	
	MICHAEL MELLER	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-12 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-12, 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of **pilocarpine in the salt form, methylcellulose, sorbitol, sodium or disodium hydrogen phosphate , magnesium stearate, polyethylene glycol, hyaluronic acid, lysozyme chlorohydrate (aka lysozyme-see below explanation)** in the reply filed on 4/13/2010 is acknowledged. The traversal is on the ground(s) that the JP 07330602 reference cited previously does not apply to the instant claims under the PCT rules. This is not found persuasive because as noted on the record, the claims are properly rejected under the cited art. Thus, a lack of unity does indeed exist. The art does teach the salt form of pilocarpine and a bioadhesive polymer such as the elected methylcellulose. The claims are being examined for the above specifically elected composition.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims do not find support for the ranges as claimed. Applicant alleges that there is support for such ranges, but such support cannot be found in the instant specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 9-12, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US 2003/0185884) in view of Frey, II (US

2001/0043915), GB 941664 and Hatsuya et al. (US 5342840) and as evidenced by "Resolution Oeno".

Singh teaches that pilocarpine and its salts are known to be formulated into a dissolving tablet, chewing tablet or the like to be used orally in the buccal cavity, see paragraphs 35, 55, 81, 84, 110, 117, abstract and the claims. Sorbitol and magnesium stearate are also used in the tablet.

Singh does not teach using hyaluronic acid, methylcellulose, lysozyme chlorohydrate, polyethylene glycol or disodium hydrogen phosphate.

Frey teaches that hyaluronic acid is used for buccal administration in tablet form, see paragraphs 86, 89.

Hatsuya teaches that methylcellulose, polyethylene glycol and disodium hydrogen phosphate are all well known common pharmaceutical components and are also used in tablet form, see col. 11, lines 27-end.

GB teaches that lysozyme which is the same as lysozyme chlorohydrate (see "Resolution Oeno") is used in sublingual tablet form, see entire reference.

It would have been obvious to one having ordinary skill in the art to use all of the claimed components together since they are known to be used in a tablet.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
>
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Indeed, the tablet is known to be in a form for sublingual administration, see Frey, GB and Singh. Thus, it was clearly within the purview of the ordinary artisan to use all of the components together to be in a single tablet used for sublingual administration.

Note that Singh teaches that 0.01-10 % of pilocarpine is used, see paragraph 87, clearly meeting the limitations in claims 21 and 22.

Claim 23 is met since it reads on such negligible amounts of lysozyme. Clearly GB teaches the use of lysozyme, see the reference. To use very small amounts of the lysozyme is clearly a results effective variable which is clearly well within the purview of the ordinary artisan in an effort to optimize the desired results.

Where the general conditions of the claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Selecting a narrow range within somewhat broader range is obvious:

> Selecting a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range. In fact, when, as here, the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.
>
> . . .

> We therefore conclude that a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness. That is not to say that the claimed composition having a narrower range is unpatentable. Rather, the existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious, as we discuss below.
>
> *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003).

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc.

v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, through routine experimentation, "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In other words, the claimed amounts were well within the purview of the ordinary artisan at the time the invention was made in an effort to optimize the desired results.

Applicant argues in their response filed 8/11/2010 that Singh allegedly teaches that pilocarpine is in lipophilic form. Applicant argues that one of ordinary skill in the art would recognize that pilocarpine is not lipophilic. Applicant argues that pilocarpine is amphiphilic. Then, applicant concludes that allegedly Singh incorrectly teaches that a pH buffer would turn an amphiphilic substance into a lipophilic one. While this is noted, it is also noted that pilocarpine is still being used by Singh. Whether applicant wants to call it an amphiphilic substance versus what Singh calls it, a lipophilic one, it is still the same compound, pilocarpine.

Applicant next alleges that Singh fails to teach or suggest any specific sublingual form or application of pilocarpine that would bring local effectiveness to the mucous floor. This is incorrect since Singh clearly teaches tablets in paragraph 55. Applicant also claims tablets thus the argument is moot.

Applicant alleges that their composition is a slow and local coating/releasing galenic structure allowing for a local mucous fixation/passage of the amphiphilic freely soluble drug. Singh also teaches a sublingual tablet which would act the same way as the claimed tablet. There is nothing on the record to prove that the tablet of Singh would not be expected to act as the instantly claimed tablet. Both the instantly claimed tablet and the one in Singh teach sublingual administration of a tablet, thus they both act the same way.

Next applicant argues that Frey allegedly teaches that the purpose of Frey and the instantly claimed invention are not one and the same. While this is noted, the instantly claimed invention and Frey do not have to have the same purpose, only Frey and Singh have to. Applicant next argues that Frey and Singh allegedly do not teach the same route of administration but clearly they both teach sublingual administration as noted above.

Applicant next argues that Hatsuya allegedly teaches tablet form but not any composition of cycloprane combined with at least one bioadhesive polymer so as to allow dissolution and local attachment to the tissues of the buccopharyngeal cavity. While this is noted it is not required. Hatsuya was cited to teach that methylcellulose, polyethylene glycol and disodium hydrogen phosphate are all well known common pharmaceutical components and are also used in tablet form, see col. 11, lines 27-end. Thus, Hatsuya does not have to teach a composition of cycloprane combined with at least one bioadhesive polymer so as to allow dissolution and local attachment to the tissues of the buccopharyngeal cavity because Hatsuya teaches that methylcellulose, polyethylene glycol and disodium hydrogen phosphate can be used in a tablet and such a tablet can be made also with pilocarpine. Methylcellulose, polyethylene glycol, disodium hydrogen phosphate, and pilocarpine have all been shown to be in tablet form, thus to use methylcellulose, polyethylene glycol and disodium hydrogen phosphate all in tablet form is obvious as is of record. One does not have to prove that cycloprane and methylcellulose can be used together since Haysuya clearly establishes that methylcellulose, polyethylene glycol, and disodium hydrogen phosphate are used in tablets and Singh has already established that pilocarpine is used in tablet form as well, thus since they were used in the art for the same purpose, namely in tablet form, then it is obvious to combine them for the reasons of record.

The tablet in Hatsuya could be used as a sublingual tablet since a tablet is placed in the mouth and sublingual is under the tongue which is in the mouth, see col. 11, lines 25-60.

Applicant argues in their response filed 2/22/2011 that Singh's tablet will perform differently than applicant's but when all of the components are all combined from the references the same tablet will be made for the reasons of record. Applicant argues that Singh fails to teach all of the components but this is a 35 USC 103 rejection and not a 35 USC 102 rejection, thus Singh does not have to teach all of the claimed components.

Applicant argues that Singh does not teach a sublingual tablet but clearly Singh teaches administration to the buccal cavity which Singh teaches includes sublingual, see paragraph 35 of Singh. Applicant argues that Singh only teaches chewing gum but this is simply false, Singh clearly teaches a tablet as claimed.

Applicant keeps arguing that the tablet of Singh will behave differently but the claims are to the components in the tablet which the references teach thus the combination is obvious and thus the claims are then obvious and unpatentable. Applicant attempts to argue that the tablet produced by the combination of

references will not work as applicant's tablet but the claims are to a product not to the method of using the product.

Applicant then argues that the references do not contain all of the components individually but once again applicant's arguments are without merit since this is a rejection based on a combination of references, thus any one reference in the combination does not have to teach all of the claimed components.

Singh clearly teaches more than chewing gum and indeed teaches tablets, see paragraph 55.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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